INDEX
to volume 13
jan-dec 1985

authors

Anderson JL: see McCutcheon ML, Apr, p 100
Auchinachie JA: see Burke EJ, Mar, p 99
Avener J: see Zucker P, Nov, p 88

Baker H: see Cohen JL, May, p 43
Baker WP: see Blair TP, Mar, p 57
Bayder S: see Zucker P, Nov, p 88
Becker GD: Barotrauma resulting from scuba diving: an otolaryngological perspective, Mar, p 112
Beckwith VZ: see Shields CL, Feb, p 49
Bednarski K: see Bunch RP, May, p 59
Bellucci PA: see Richie DH, Feb, p 130
Benson J: Inadequate nutrition and chronic calorie restriction in adolescent ballerinas, Oct, p 79
Berman P: see Ryan AJ, Vision, eye care, and the athlete
Bianco L: see Hanke CW, Aug, p 51
Bishop P: see Sintek S, May, p 119
Bixby-Hammett DM: Youth accidents with horses, Sep, p 105
Blair TP: Case reports: atrial fibrillation and flutter in athletes, Mar, p 57
Blanchard MS: see Tomassoni TL, Nov, p 110
Blyth CS: see Mueller FO, Mar, p 75
Boitano MA: Driver injuries in auto road racing, Aug, p 122
Bourdet K: see Benson J, Oct, p 79
Bracker MD: How I manage travelers' diarrhea, Nov, p 63
Braun JK: see Speer DP, Jul, p 72
Brotman A: see Zucker P, Nov, p 88
Bugaieski SM: see Sidler GJ, Jul, p 113
Bunch RP: Ankle joint support: a comparison of reusable lace-on braces with taping and wrapping, May, p 59
Burke EJ: Energy cost of wheelchair basketball, Mar, p 99

Caine DJ: Overuse injuries of growing bones: the young female gymnast at risk?, Dec, p 51
Campaigne BN: The effects of physical training on blood lipid profiles in adolescents with insulin-dependent diabetes mellitus, Dec, p 83
Campbell P: see Silver DM, Nov, p 75
Casey JK: see Jones BH, Oct, p 103
Catlin DH: see Strauss RH, Dec, p 69
Chandy TA: Secondary school athletic injury in boys and girls: a three-year comparison, Mar, p 106
Clancy WG: University of Wisconsin Hospital Sports Medicine and Fitness Center, Jan, p 42
Clement DB: see Lloyd-Smith R, Oct, p 131
Cohen JL: A nutritional and hematologic assessment of elite ballet dancers, May, p 43
Coniglione TC: see Grana WA, May, p 127
Costill DL: Effects of reduced training on muscular power in swimmers, Feb, p 94

Davis GM: see Plyley MJ, Jun, p 152
Demment R: see Miller D, Jan, p 67
deShazo WF: see Gaskins SE, Sep, p 93
Dick A: see McCarroll JR, Jun, p 121
Dickson TB: Preventing overuse cycling injuries, Oct, p 116
Diehl RC: see Hansen BL, Sep, p 75
Dressendorfer RH: Increased morning heart rate in runners: a valid sign of overtraining?, Aug, p 77

Eddings K: see Jones BH, Oct, p 103
Ellsworth NM: Nutrient intake of elite male and female Nordic skiers, Feb, p 78
Epstein JH: How I manage sunburn, Jul, p 81
Ewy GA: see Wilmore JH, Jul, p 60

Finn JA: Competitive excellence: it's a matter of mind and body, Feb, p 61
Fleagle SB: see Whiteside JA, Jan, p 102
Francis LL: Aerobic dance injuries: a survey of instructors, Feb, p 105
Francis PR: see Francis LL, Feb, p 102
Frank O: see Cohen JL, May, p 43
Freund BJ: see Wilmore JH, Jul, p 60

Garner AI: see Ryan AJ, Vision, eye care, and the athlete
Garrick JG: Characterization of the patient population in a sports medicine facility, Oct, p 73
Garrick JG: The fitness facility as a rehabilitation care extender, Oct, p 61
Gaskins SE: Attitudes toward drug abuse and screening for an intercollegiate athletic program, Sep, p 93
Gillien DM: see Benson J, Oct, p 79
Glueck CJ: see Campaigne BN, Dec, p 83
Goldberg R: see Gurry M, Jun, p 63
Goldfarb AH: see Tomassoni TL, Nov, p 110
Goldman RM: The effects of oscillating inversion on systemic blood pressure, pulse, intraocular pressure, and central retinal arterial pressure, Mar, p 93
Goldman RM: see Klatz RM, Mar, p 85
Goodman PH: Stress fracture diagnosis by computer-assisted thermography, Apr, p 114
Grana WA: Knee disorders in runners, May, p 127
Grana WA: see Chandy TA, Mar, p 106
Greipp JF: Swimmer's shoulder: the influence of flexibility and weight training, Aug, p 92
Griffey MS: see May JR, Oct, p 111
Gurry M: A comprehensive preseason fitness evaluation for professional baseball players, Jun, p 63

Hanke CW: Skin cancer in professional and amateur female golfers, Aug, p 51
Hansen BL: The preventive use of the Anderson knee stabler in football, Sep, p 75
Hargreaves M: see Costill DL, Feb, p 94
Haskell WL: see Ellsworth NM, Feb, p 78
Hayden R: see Burke EJ, Mar, p 99
Heaslet MW: see Goodman PH, Apr, p 114
Helfet DL: see Vetter WL, Feb, p 114
Hempel LS: Cardiorespiratory cost of the Nautilus Express Circuit, Apr, p 82
Hewitt BF: see Ellsworth NM, Feb, p 78
Holland D: see Bunch RP, May, p 59
Hoontis PP: see Rowland TW, Mar, p 126
Hughes WA: Distance race injuries: an analysis of runners' perceptions, Nov, p 43

Jackson AS: Practical assessment of body composition, May, p 76
James FW: see Campaigne BN, Dec, p 83
Jones BH: Medical complaints after a marathon run in cool weather, Oct, p 103
Joyner MJ: see Wilmore JH, Jul, p 60

Kalenak A: see Whiteside JA, Jan, p 102
Kappler RE: see Goldman RM, Mar, p 93
Kelso SF: see Richie DH, Feb, p 130
King DS: see Costill DL, Feb, p 94
Kirkendall DT: The applied sport science of soccer, Apr, p 53
Klatz RM: Effects of gravity inversion on hypertensive subjects, Mar, p 85
Kozey J: see Stanish WD, Aug, p 108
Kurland HL: see Shields CL, Feb, p 49

Landry GL: What is the role of a pediatrician within a sports medicine program?, Jan, p 51
Landt KW: see Campaigne BN, Dec, p 83
Larson DC: Toxic vapor exposure and aerobic exercise, Jan, p 76
Leslie SW: Congenital ureteropelvic junction obstruction: abdominal pain in runners, Jul, p 105
Lindner KJ: see Caine DJ, Dec, p 51
Litel GR: see Ryan AJ, The medical aspects of boxing
Lloyd-Smith R: A survey of overuse and traumatic hip and pelvic injuries in athletes, Oct, p 131
Loftin JM: see Burke EJ, Mar, p 99
Loke J: see Mahler DA, Jan, p 84
Lombardo JA: Sports medicine: a team effort, Apr, p 72
Loosli AR: see Benson J, Oct, p 79

INDEX
to volume 13
jan-dec 1985

authors

Anderson JL: see McCutcheon ML, Apr, p 100
Auchinachie JA: see Burke EJ, Mar, p 99
Avener J: see Zucker P, Nov, p 88

Baker H: see Cohen JL, May, p 43
Baker WP: see Blair TP, Mar, p 57
Bayder S: see Zucker P, Nov, p 88
Becker GD: Barotrauma resulting from scuba diving: an otolaryngological perspective, Mar, p 112
Beckwith VZ: see Shields CL, Feb, p 49
Bednarski K: see Bunch RP, May, p 59
Bellucci PA: see Richie DH, Feb, p 130
Benson J: Inadequate nutrition and chronic calorie restriction in adolescent ballerinas, Oct, p 79
Berman P: see Ryan AJ, Vision, eye care, and the athlete
Bianco L: see Hanke CW, Aug, p 51
Bishop P: see Sintek S, May, p 119
Bixby-Hammett DM: Youth accidents with horses, Sep, p 105
Blair TP: Case reports: atrial fibrillation and flutter in athletes, Mar, p 57
Blanchard MS: see Tomassoni TL, Nov, p 110
Blyth CS: see Mueller FO, Mar, p 75
Boitano MA: Driver injuries in auto road racing, Aug, p 122
Bourdet K: see Benson J, Oct, p 79
Bracker MD: How I manage travelers' diarrhea, Nov, p 63
Braun JK: see Speer DP, Jul, p 72
Brotman A: see Zucker P, Nov, p 88
Bugaieski SM: see Sidler GJ, Jul, p 113
Bunch RP: Ankle joint support: a comparison of reusable lace-on braces with taping and wrapping, May, p 59
Burke EJ: Energy cost of wheelchair basketball, Mar, p 99

Caine DJ: Overuse injuries of growing bones: the young female gymnast at risk?, Dec, p 51
Campaigne BN: The effects of physical training on blood lipid profiles in adolescents with insulin-dependent diabetes mellitus, Dec, p 83
Campbell P: see Silver DM, Nov, p 75
Casey JK: see Jones BH, Oct, p 103
Catlin DH: see Strauss RH, Dec, p 69
Chandy TA: Secondary school athletic injury in boys and girls: a three-year comparison, Mar, p 106
Clancy WG: University of Wisconsin Hospital Sports Medicine and Fitness Center, Jan, p 42
Clement DB: see Lloyd-Smith R, Oct, p 131
Cohen JL: A nutritional and hematologic assessment of elite ballet dancers, May, p 43
Coniglione TC: see Grana WA, May, p 127
Costill DL: Effects of reduced training on muscular power in swimmers, Feb, p 94

Davis GM: see Plyley MJ, Jun, p 152
Demment R: see Miller D, Jan, p 67
deShazo WF: see Gaskins SE, Sep, p 93
Dick A: see McCarroll JR, Jun, p 121
Dickson TB: Preventing overuse cycling injuries, Oct, p 116
Diehl RC: see Hansen BL, Sep, p 75
Dressendorfer RH: Increased morning heart rate in runners: a valid sign of overtraining?, Aug, p 77

Eddings K: see Jones BH, Oct, p 103
Ellsworth NM: Nutrient intake of elite male and female Nordic skiers, Feb, p 78
Epstein JH: How I manage sunburn, Jul, p 81
Ewy GA: see Wilmore JH, Jul, p 60

Finn JA: Competitive excellence: it's a matter of mind and body, Feb, p 61
Fleagle SB: see Whiteside JA, Jan, p 102
Francis LL: Aerobic dance injuries: a survey of instructors, Feb, p 105
Francis PR: see Francis LL, Feb, p 102
Frank O: see Cohen JL, May, p 43
Freund BJ: see Wilmore JH, Jul, p 60

Garner AI: see Ryan AJ, Vision, eye care, and the athlete
Garrick JG: Characterization of the patient population in a sports medicine facility, Oct, p 73
Garrick JG: The fitness facility as a rehabilitation care extender, Oct, p 61
Gaskins SE: Attitudes toward drug abuse and screening for an intercollegiate athletic program, Sep, p 93
Gillien DM: see Benson J, Oct, p 79
Glueck CJ: see Campaigne BN, Dec, p 83
Goldberg R: see Gurry M, Jun, p 63
Goldfarb AH: see Tomassoni TL, Nov, p 110
Goldman RM: The effects of oscillating inversion on systemic blood pressure, pulse, intraocular pressure, and central retinal arterial pressure, Mar, p 93
Goldman RM: see Klatz RM, Mar, p 85
Goodman PH: Stress fracture diagnosis by computer-assisted thermography, Apr, p 114
Grana WA: Knee disorders in runners, May, p 127
Grana WA: see Chandy TA, Mar, p 106
Greipp JF: Swimmer's shoulder: the influence of flexibility and weight training, Aug, p 92
Griffey MS: see May JR, Oct, p 111
Gurry M: A comprehensive preseason fitness evaluation for professional baseball players, Jun, p 63

Hanke CW: Skin cancer in professional and amateur female golfers, Aug, p 51
Hansen BL: The preventive use of the Anderson knee stabler in football, Sep, p 75
Hargreaves M: see Costill DL, Feb, p 94
Haskell WL: see Ellsworth NM, Feb, p 78
Hayden R: see Burke EJ, Mar, p 99
Heaslet MW: see Goodman PH, Apr, p 114
Helfet DL: see Vetter WL, Feb, p 114
Hempel LS: Cardiorespiratory cost of the Nautilus Express Circuit, Apr, p 82
Hewitt BF: see Ellsworth NM, Feb, p 78
Holland D: see Bunch RP, May, p 59
Hoontis PP: see Rowland TW, Mar, p 126
Hughes WA: Distance race injuries: an analysis of runners' perceptions, Nov, p 43

Jackson AS: Practical assessment of body composition, May, p 76
James FW: see Campaigne BN, Dec, p 83
Jones BH: Medical complaints after a marathon run in cool weather, Oct, p 103
Joyner MJ: see Wilmore JH, Jul, p 60

Kalenak A: see Whiteside JA, Jan, p 102
Kappler RE: see Goldman RM, Mar, p 93
Kelso SF: see Richie DH, Feb, p 130
King DS: see Costill DL, Feb, p 94
Kirkendall DT: The applied sport science of soccer, Apr, p 53
Klatz RM: Effects of gravity inversion on hypertensive subjects, Mar, p 85
Kozey J: see Stanish WD, Aug, p 108
Kurland HL: see Shields CL, Feb, p 49

Landry GL: What is the role of a pediatrician within a sports medicine program?, Jan, p 51
Landt KW: see Campaigne BN, Dec, p 83
Larson DC: Toxic vapor exposure and aerobic exercise, Jan, p 76
Leslie SW: Congenital ureteropelvic junction obstruction: abdominal pain in runners, Jul, p 105
Lindner KJ: see Caine DJ, Dec, p 51
Litel GR: see Ryan AJ, The medical aspects of boxing
Lloyd-Smith R: A survey of overuse and traumatic hip and pelvic injuries in athletes, Oct, p 131
Loftin JM: see Burke EJ, Mar, p 99
Loke J: see Mahler DA, Jan, p 84
Lombardo JA: Sports medicine: a team effort, Apr, p 72
Loosli AR: see Benson J, Oct, p 79

Lundberg GD: see Ryan AJ, The medical aspects of boxing

MacGillvary G: see Stanish WD, Aug, p 108
Macinanti R: see Bunch RP, May, p 59
Maguire DL: Popliteal artery occlusion in a wrestler in the absence of known trauma, Aug, p 139
Maher P: see Gurry M, Jun, p 63
Mahler DA: The physiology of marathon running, Jan, p 84
Malkin LH: see Jones BH, Oct, p 103
Matthew WT: see Jones BH, Oct, p 103
Matthews LS: see Vetter WL, Feb, p 114
May JR: A psychological study of health, injury, and performance in athletes on the US Alpine Ski Team, Oct, p 111
McCarroll JR: Anterior cruciate ligament injuries in relay tricycle racing, Jun, p 121
McCormick DP: Skiing injuries in handicapped Alpine ski racers, Dec, p 93
McCue FC: How I manage fractured metacarpals in athletes, Sep, p 85
McCunney RJ: see Ryan AJ, The medical aspects of boxing
McCutcheon ML: How I manage sports injuries to the larynx, Apr, p 100
McKenzie DC: see Lloyd-Smith R, Oct, p 131
Medford HM: Third molars: asset or liability for college athletes?, Jun, p 111
Mellies MJ: see Campaigne BN, Dec, p 83
Michaels J: see Gurry M, Jun, p 63
Miller D: Fitness evaluations for recreational athletes, Jan, p 67
Moore K: see Zucker P, Nov, p 88
Morgan JP: see Strauss RH, Dec, p 69
Morton AR: see Wilmore JH, Jul, p 60
Mueller FO: Annual survey of catastrophic football injuries: 1977 to 1983, Mar, p 75
Murphy RJ: see Strauss RH, Dec, p 69
Murray TH: see Strauss RH, Dec, p 69

Noble HB: see Hughes WA, Nov, p 43
Novich MN: see Ryan AJ, The medical aspects of boxing

O'Brian JJ: see Hanke CW, Aug, p 51

Pagliano JW: see Goodman PH, Apr, p 114
Pappas A: see Gurry M, Jun, p 63
Pashby RC: see Ryan AJ, Vision, eye care, and the athlete
Percy EC: Patellalgia, Jul, p 43
Perry WJ: Exertional headache, Oct, p 95
Pinchuk BG: see Goldman RM, Mar, p 93
Pinchuk BG: see Klatz RM, Mar, p 85
Pyley MJ: Body profile of Olympic-class sailors, Jun, p 152
Pollock ML: see Jackson AS, May, p 76
Porter M: see Hughes WA, Nov, p 43
Potosnak L: see Cohen JL, May, p 43
Puffer JC: see Strauss RH, Dec, p 69

Ray RR: see Maguire DL, Aug, p 139
Reed MW: see May JR, Oct, p 111
Richards NG: see Ryan AJ, The medical aspects of boxing
Richie DH: Aerobic dance injuries: a retrospective study of instructors and participants, Feb, p 130
Rippe J: see Gurry M, Jun, p 63.
Rock PB: see Jones BH, Oct, p 103
Rowland TW: Characteristics of child distance runners, Sep, p 45
Rowland TW: Organizing road races for children: special concerns, Mar, p 126
Rubin BD: see Goodman PH, Apr, p 114
Rubinovich M: see Stanish WD, Aug, p 108
Ryan AJ: The medical aspects of boxing (round table), Sep, p 56
Ryan AJ: Vision, eye care, and the athlete (round table), Jun, p 132

Scaff JH: see Dressendorfer RH, Aug, p 77
Shakman A: see Gurry M, Jun, p 63
Shephard RJ: Motivation: the key to fitness compliance, Jul, p 88
Shephard RJ: see Plyley MJ, Jun, p 152
Sherman A: see Ryan AJ, Vision, eye care, and the athlete
Sherman B: A new approach to athletic training in southern Wisconsin high schools, Jan, p 57
Shields CL: Comparison of leg strength training equipment, Feb, p 49
Sidler GJ: Difficulty in diagnosing and treating deep vein thrombosis in a competitive basketball player, Jul, p 113
Silver DM: Arthroscopic assessment and treatment of dancers' injuries, Nov, p 74
Sintek S: Physicians' perceptions of using physical education for managing childhood obesity, May, p 119
Smith LS: see Jones BH, Oct, p 103
Spear K: see Vetter WL, Feb, p 114
Speer DP: The biomechanical basis of growth plate injuries, Jul, p 72
Sperling MA: see Campaigne BN, Dec, p 83
Stanish WD: The use of electricity in ligament and tendon repair, Aug, p 108
Strauss RH: Drug testing in sports (round table), Dec, p 69
Strother RT: see Percy EC, Jul, p 43
Sunderlin J: see Sidler GJ, Jul, p 113

Tarr RS: see Goldman RM, Mar, p 93
Tarr RS: see Klatz RM, Mar, p 85
Taunton JE: see Lloyd-Smith R, Oct, p 131
Teves MA: see Jones BH, Oct, p 103
Thomas R: see Costill DL, Feb, p 94
Tifft CP: see Walther RJ, May, p 92
Tomassoni TL: Effects of a rebound exercise program on aerobic capacity and body composition, Nov, p 110
Tudor RB: see Leslie SW, Jul, p 105

Veach TL: see May JR, Oct, p 111
Vetter WL: Aerobic dance injuries, Feb, p 114
Vinger PF: see Ryan AJ, Vision, eye care, and the athlete
Voy RO: see Strauss RH, Dec, p 69

Wade CE: see Dressendorfer RH, Aug, p 77
Walsh CA: see Rowland TW, Sep, p 45
Walsh M: Preventing injury in competitive canoeists, Sep, p 120
Walther RJ: High blood pressure in the competitive athlete: guidelines and recommendations, May, p 92
Ward JC: see Hansen BL, Sep, p 75
Weiker GG: Injuries in club gymnastics, Apr, p 63
Weller HW: see Whiteside JA, Jan, p 102
Wells CL: see Hempel LS, Apr, p 82
Welshons-Smith K: see Francis LL, Feb, p 105
Weltman A: see Sidler GJ, Jul, p 113
Whiteside JA: Manpower loss in football: a 12-year study at The Pennsylvania State University, Jan, p 102
Wilkerson GB: External compression for controlling traumatic edema, Jun, p 96
Wilkerson GB: Treatment of ankle sprains with external compression and early mobilization, Jun, p 83
Wilmore JH: Beta-blockade and response to exercise: influence of training, Jul, p 60

Zimmerman J: see Zucker P, Nov, p 88
Zollinger TW: see Hanke CW, Aug, p 51
Zonnebelt SM: see Maguire DL, Aug, p 139
Zucker P: Eating disorders in young athletes (round table), Nov, p 88

subjects

Abdomen
ureteropelvic junction obstruction in long-distance runners, Jul, p 105
Adolescents
age vs size in junior high school football, Jun, p 38
diabetic, benefit from exercise program, Dec, p 83
distance runners, characteristics of, Sep, p 45
eating disorders in athletes, Nov, p 88
health care at the University of Wisconsin Hospital Sports Medicine and Fitness Center, Jan, p 51; p 57
health care in secondary schools, Mar, p 169
horse-related accidents, Sep, p 105
learning-disabled children benefit from sports participation, Jun, p 39
nutrition inadequate in ballerinas, Oct, p 79
overuse injuries in young female gymnasts, Dec, p 51
physical education: reemphasis needed, Jan, p 30
sports injuries in boys and girls: a three-year comparison, Mar, p 106
training programs for coaches, Apr, p 136
continued

Aerobic dance: see Dance
Aerobic exercise: see Exercise
Air pollution
toxic vapor exposure and aerobic exercise, Jan, p 76
Allergy
reactions to exercise (letter), Apr, p 15
Altitude
sickness, Nov, p 36
American Academy of Pediatrics
strong statements made at Atlanta meeting, Aug, p 32
American Alliance for Health, Physical Education, Recreation, and Dance
fitness: school children to be tested nationwide, Sep, p 28
American College of Sports Medicine
certification standards for fitness instructors revised, Jul, p 32
1985 annual meeting: questions and answers, Aug, p 145
American Medical Association
drug abuse by athletes discussed, Apr, p 25
Anaphylaxis: see Allergy
Ankle injuries
sprains, treated with external compression and early mobilization, Jun, p 83
supports evaluated, May, p 59
a 12-year study of football injuries at The Pennsylvania State University, Jan, p 102
Arm injuries
in baseball, Jun, p 181; (correction) Nov, p 15
in canoeists and kayakers: prevention and treatment, Sep, p 120
Arthroscopy
for knee injuries in dancers
Auto racing
injuries in professional and amateur drivers, Aug, p 122

Ballet: see Dance
Barotrauma
from scuba diving, Mar, p 112
Baseball
fitness evaluation of a professional team, Jun, p 63
mandatory drug testing in the major leagues, Jul, p 32
players becoming leaner, Jun, p 38
visual skills of professional players tested, Mar, p 37
Baseball injuries
throwing arm, Jun, p 181; (correction) Nov, p 15
Basketball
wheelchair, energy costs of, Mar, p 99
Bicycling injuries
anterior cruciate ligament injuries in relay tricycle racing, Jun, p 121
overuse, prevention of, Oct, p 116
Blood
doping ban: more bark than bite?, Aug, p 32
doping: ethics (colloquium, ACSM annual meeting), Aug, p 145
lipid profiles in diabetic adolescents after exercise, Dec, p 83
Body composition
assessment of, May, p 76
baseball players becoming leaner, Jun, p 38
electrical impedance for measuring body fat: pros and cons, Nov, p 124
and rebound exercise, Nov, p 110
Bone
computer-assisted thermography for diagnosing stress fractures, Apr, p 114
osteoporosis and calcium, Sep, p 179
Boxing
AMA calls for ban, Feb, p 31
legislation: three bills pending in Congress, Jul, p 33
medical aspects, Sep, p 56
Novich (Max) defends, Apr, p 145

Canada
fishing around Winnipeg, May, p 179
women lack fitness, survey shows, Jan, p 30
Casts
protective pads for athletes, Mar, p 179
Cheerleading
safety guidelines needed, Nov, p 39
Children in sports
age vs size in junior high school football, Jun, p 38
American Academy of Pediatrics issues strong statements at Atlanta meeting, Aug, p 32
distance runners, characteristics of, Sep, p 45
eating disorders in athletes, Nov, p 88
growth plate injuries: anatomical and biomechanical aspects, Jul, p 72
health care at the University of Wisconsin Hospital Sports Medicine and Fitness Center, Jan, p 51
heart disease risk factors reduced, study shows, Feb, p 34
horse-related accidents, Sep, p 105
learning-disabled benefit from participation, Jun, p 39
organizing road races, Mar, p 126
overuse injuries in young female gymnasts, Dec, p 51
physical education for childhood obesity, May, p 119
physical education: reemphasis needed, Jan, p 30
training programs for coaches, Apr, p 136
Clinics and centers
fitness facilities and rehabilitation, Oct, p 61
health club atmosphere motivates patients in new rehabilitation clinic, Sep, p 28
how to start a sports medicine clinic, Jun, p 168
performing artists treated at new institute, Sep, p 175
profile of patients in a sports medicine facility, Oct, p 73
University of Wisconsin Hospital Sports Medicine and Fitness Center, Jan, p 42; p 51; p 57; p 67
Coaching
training programs for youth coaches, Apr, p 136
Cold
medical complaints in runners after cool-weather marathons, Oct, p 103
Computers
computer-assisted thermography for diagnosing stress fractures, Apr, p 114

Dance
aerobic: injuries, Feb, p 114; p 130
aerobic: injuries in instructors, Feb, p 105
ballet dancers need nutrition counseling, May, p 43
knee injuries in dancers: arthroscopic assessment and treatment, Nov, p 74
nutrition inadequate in adolescent ballerinas, Oct, p 79
Death
football fatalities drop in 1984, May, p 28
Deep vein thrombosis
in a high school basketball player, Jul, p 113
Dehydration
prevention and treatment, Mar, p 176
Dental care
wisdom teeth in college athletes, Jun, p 111
Diabetes
adolescents benefit from exercise program, Dec, p 51
and exercise, Sep, p 164
Diarrhea
travelers': prevention and treatment, Apr, p 26; Nov, p 63
Diving injuries
barotrauma from scuba diving, Mar, p 112
decompression sickness, Sep, p 30
Drugs
alcohol and ski injuries, May, p 27
AMA discusses abuse by athletes, Apr, p 25
attitudes toward abuse and screening in college athletes, Sep, p 93
beta-blockers, exercise, and training, Jul, p 60
blood doping, Mar, p 37
caffeine and sports performance, May, p 191
mandatory testing in major league baseball, Jul, p 32
NCAA testing proposal set for January vote, Dec, p 49
NCAA testing proposal stalled, Apr, p 26
Olympic cyclists try caffeine suppositories, Mar, p 38
soda loading, May, p 28
steroids: 4% of athletes surveyed used them (NCAA study), Aug, p 30
stiffer penalties for Olympic abusers, Jul, p 31
testing in sports, Dec, p 46; p 69

Ear injuries
barotrauma from scuba diving, Mar, p 112
Eating disorders
in young athletes, Nov, p 88
Electrical stimulation
for ligament and tendon repair, Aug, p 108
Epiphysis
anatomical and biomechanical aspects of in-

continued

Brief Summary: ANAPROX® (naproxen sodium)
Indications: Relief of mild to moderate pain; treatment of primary dysmenorrhea.
Contraindications: Patients who have had allergic reactions to NAPROSYN or ANAPROX or in whom aspirin or other NSAIDs induce the syndrome of asthma, rhinitis, and nasal polyps.
Warnings: GI bleeding, sometimes severe, and occasionally fatal, has been reported. Do not give to patients with active peptic ulcer unless potential benefit outweighs risk. Administer to those and others with history of GI disease only under close supervision.
Precautions: DO NOT GIVE *NAPROSYN®* (NAPROXEN) CONCOMITANTLY WITH *ANAPROX®* (NAPROXEN SODIUM) SINCE BOTH CIRCULATE IN PLASMA AS THE NAPROXEN ANION. Because anaphylactic reactions usually occur in patients with a history of such reactions, question patients for asthma, nasal polyps, urticaria, and hypotension associated with NSAIDs before starting therapy. If such symptoms occur, discontinue the drug. Acute interstitial nephritis with hematuria, proteinuria, and nephrotic syndrome has been reported. Patients with impaired renal function, heart failure, liver dysfunction, taking diuretics, and the elderly are at greater risk of overt renal decompensation. If this occurs, discontinue the drug. Use with caution and monitor serum creatinine and/or creatinine clearance in patients with significantly impaired renal function. Use caution in patients with baseline creatinine clearance less than 20 ml/minute. Use caution when high doses are required in the elderly or in patients with chronic alcoholic liver disease or cirrhosis. With NSAIDs, borderline elevations of liver tests may occur in up to 15% of patients. They may progress, remain unchanged, or be transient with continued therapy. Elevations of SGPT or SGOT occurred in controlled clinical trials in less than 1% of patients. Severe hepatic reactions, including jaundice and fatal hepatitis, have been reported rarely. If liver disease develops or if systemic manifestations occur (e.g., eosinophilia or rash), discontinue therapy. If steroid dosage is reduced or eliminated during therapy, do so slowly and observe patients closely for adverse effects, including adrenal insufficiency and exacerbation of arthritis symptoms. Determine hemoglobin values frequently for patients with initial values of 10 grams or less who receive long-term therapy. Peripheral edema has been reported. For patients with restricted sodium intake, note that each tablet contains approximately 25 mg (1 mEq) sodium. Use with caution in patients with fluid retention, hypertension or heart failure. The drug's antipyretic and anti-inflammatory activities may reduce fever and inflammation, diminishing their diagnostic value. Conduct ophthalmic studies soon after starting therapy and at periodic intervals if the drug is used for an extended period.
Information for Patients: Patients should use caution for activities requiring alertness if they experience drowsiness, dizziness, vertigo or depression during therapy.
Drug Interactions: Use caution when giving concomitantly with coumarin-type anticoagulants; a hydantoin, sulfonamide or sulfonylurea; furosemide; lithium; beta-blockers; probenecid; or methotrexate.
Drug/Laboratory Test Interactions: The drug may decrease platelet aggregation and prolong bleeding time or increase urinary values for 17-ketogenic steroids. Temporarily stop therapy for 72 hours before doing adrenal function tests. The drug may interfere with urinary assays of 5HIAA.
Carcinogenesis: A 2-year rat study showed no evidence of carcinogenicity.
Pregnancy: Category B. Do not use during pregnancy unless clearly needed. Avoid use during late pregnancy.
Nursing Mothers: Avoid use in nursing mothers.
Pediatric Use: Indications and dosage have not been established.
Adverse Reactions: Incidence Greater Than 1%: GI: The most frequent complaints related to the GI tract: constipation,* heartburn,* abdominal pain,* nausea,* dyspepsia, diarrhea, stomatitis. CNS: headache,* dizziness,* drowsiness,* lightheadedness, vertigo. Dermatologic: itching (pruritis),* skin eruptions,* ecchymoses,* sweating, purpura. Special Senses: tinnitus,* hearing disturbances, visual disturbances. Cardiovascular: edema,* dyspnea,* palpitations. General: thirst. *Incidence of reported reaction 3%-9%. Where unmarked, incidence less than 3%. Incidence Less Than 1%: Probable Causal Relationship: GI: abnormal liver function tests, GI bleeding and/or perforation, hematemesis, jaundice, melena, peptic ulceration with bleeding and/or perforation, vomiting. Renal: glomerular nephritis, hematuria, interstitial nephritis, nephrotic syndrome, renal disease. Hematologic: eosinophilia, granulocytopenia, leukopenia, thrombocytopenia. CNS: depression, dream abnormalities, inability to concentrate, insomnia, malaise, myalgia and muscle weakness. Dermatologic: alopecia, skin rashes. Special Senses: hearing impairment. Cardiovascular: congestive heart failure. Respiratory: eosinophilic pneumonitis. General: anaphylactoid reactions, menstrual disorders, pyrexia (chills and fever). Causal Relationship Unknown: Hematologic: agranulocytosis, aplastic anemia, hemolytic anemia. CNS: cognitive dysfunction. Dermatologic: urticaria. GI: ulcerative stomatitis. General: angioneurotic edema, hyperglycemia, hypoglycemia.
Overdosage: May have drowsiness, heartburn, indigestion, nausea, vomiting. Empty stomach and use usual supportive measures. Prompt administration of 5 grams activated charcoal may reduce drug absorption.
Dosage and Administration for Mild to Moderate Pain, Dysmenorrhea and Acute Tendinitis and Bursitis: The recommended starting dose is two 275 mg tablets, followed by one 275 mg tablet every 6 to 8 hours, as required. The total daily dose should not exceed 5 tablets (1375 mg).
Caution: Federal law prohibits dispensing without prescription.
See package insert for full Prescribing Information.

#22
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SYNTEX
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PALO ALTO, CALIFORNIA 94304

index continued

juries in children, Jul, p 72
Equipment
ankle supports evaluated, May, p 59
braces for the unstable knee, Feb, p 142; (letter) Jun, p 21
compression pads for sprained ankle, Jun, p 83
for eye protection, Jun, p 132
football helmets and legal liability, Feb, p 161
hockey face guards to be required for high school players, Jan, p 29
inversion devices: effects on hypertensive subjects, Mar, p 85
inversion devices: oscillating, effects of, Mar, p 93; Jul, p 15
knee braces, prophylactic, in football, Sep, p 27; p 75
knee braces: prophylactic, rehabilitative, functional (an overview), Sep, p 153
knee braces: required for USFL linemen, Jun, p 37
leg strength training, compared, Feb, p 49
mirrored sunglasses can cause burn (letter), Mar, p 16
to prevent eye injuries, Feb, p 32
protective pads for athletes, Mar, p 179
ski bindings leave knee vulnerable, Dec, p 99
stationary cycles, Oct, p 161
wheelchairs: improved design enhances athletic performance, Oct, p 156
Exercise: see also Exercise prescription, Testing procedures, Training
aerobic, and toxic vapor exposure, Jan, p 76
aerobic vs anaerobic, Sep, p 186
allergic reactions and their preventive treatment (letter), Apr, p 15
calisthenics still useful, Nov, p 149
Canadian women lack fitness, survey shows, Jan, p 30
cardiovascular fitness vs physical activity for health, Mar, p 145; (letter) Jun, p 21
city parks: untapped resource for fitness, Jul, p 120
and diabetes, Sep, p 164
diabetic adolescents benefit from program, Dec, p 51
diet, appetite, and holiday treats, Dec, p 115
executives' health: Asia vs US, Jun, p 40
motivation and compliance, Jul, p 88
muscle fatigue and lactic acid, Jun, p 193
myths, fads, and fallacies, May, p 156
Nautilus Express Circuit and cardiorespiratory fitness, Apr, p 82
objectives for 1990 may not be reached, Oct, p 50
and office stress (letter), Mar, p 16
and pregnancy, Aug, p 145
rebound, effects of, Nov, p 110
rebound, fitness benefits uncertain, Sep, p 141
rebound, pros and cons, Sep, p 141
risks vs benefits, May, p 136
stationary cycling: benefits of, types of cycles, Oct, p 161
training and beta-blockers, Jul, p 60
water sports, fitness benefits of, Aug, p 180
wheelchair basketball enhances cardiovascular fitness, Mar, p 99
Exercise leaders
certification standards revised by ACSM, Jul, p 32
instructor certification, Oct, p 142
Exercise prescription
for diabetics, Sep, p 164
fitness facilities and rehabilitation, Oct, p 61
hypertension: guidelines for athletes, May, p 92
Exercise testing
measuring your aerobic fitness, Feb, p 194
predicting your aerobic fitness, Mar, p 183
training and beta-blockers, Jul, p 60
at the University of Wisconsin Hospital Sports Medicine and Fitness Center, Jan, p 67
Eye injuries
preventable with protective equipment, Feb, p 32
vision, eye care, and the athlete, Jun, p 132

Facial injuries
hockey face guards to be required for high school players, Jan, p 29
Female athletes
nutrient intake in Nordic skiers, Feb, p 78
nutrition inadequate in adolescent ballerinas, Oct, p 79
runners eat little, Aug, p 30
skin cancer in golfers, Aug, p 51
Finger injuries
taping a mallet finger, Nov, p 140
Fishing
in the Winnipeg area, May, p 179
Flexibility
and swimmer's shoulder, Aug, p 92
Fluid replacement
prevention and treatment of dehydration, Mar, p 176
Foot injuries
Sorbothane pads for treatment, protection, Jan, p 139
Football
age vs size in junior high school, Jun, p 38
helmets safer, but liability claims increase, Feb, p 161
knee braces: required for USFL linemen, Jun, p 37
NFLPA wants turf studies, Sep, p 29
Football injuries
Anderson knee stabler, Sep, p 75
catastrophic: annual survey, 1977-1983, Mar, p 75
fatalities drop in 1984, May, p 28
head and neck, still frequent, Aug, p 29
knee braces, prophylactic, Sep, p 27
a 12-year study at The Pennsylvania State University, Jan, p 102
Fractures
metacarpal, Sep, p 83
stress: diagnosis by computer-assisted thermography, Apr, p 114

Golf
skin cancer in female golfers, Aug, p 51
Government agencies
city parks: untapped resource for fitness, Jul, p 120
DRGs and cardiac rehabilitation, Sep, p 159
Gymnastics
bracing against wrist hyperextension, Apr, p 163
injuries in club gymnasts, Apr, p 63
overuse injuries in young females, Dec, p 51

Hand injuries
fractured metacarpals, Sep, p 83
Handicapped athletes
injuries in skiers, Dec, p 93
learning-disabled children benefit from sports participation, Jun, p 39
wheelchair basketball, energy cost of, Mar, p 99
wheelchair racing, Oct, p 156
Head injuries
football, still frequent, Aug, p 29
Headache
exertional, Oct, p 95
Health promotion
exercise programs, motivation, and compliance, Jul, p 88
exercise programs for reducing office stress (letter), Mar, p 16
fitness objectives for 1990 may not be reached, Oct, p 50
Heart
hypertension: guidelines for athletes, May, p 92
increased early morning heart rate in marathoners, Aug, p 77
Heart disease
atrial fibrillation and flutter in athletes, Mar, p 57
beta-blockers, exercise, and training, Jul, p 60
cardiac rehabilitation and DRGs, Sep, p 159
heart disease risk factors in children reduced, study shows, Feb, p 34
Heat stress
diagnosis, treatment vary, Jul, p 134
prevention and treatment of dehydration, Mar, p 176
Hip injuries
overuse and traumatic, Oct, p 131
Hockey
face guards to be required for high school players, Jan, p 29
fitness and conditioning programs for professional players, Nov, p 119
Hockey injuries
eye injuries preventable, Feb, p 32
Horseback riding
youth accidents, Sep, p 105
Hypertension
beta-blockers, exercise, and training, Jul, p 60
effects of inversion, Mar, p 85
guidelines for athletes, May, p 92
Hyperventilation
in athletes: treatment of, Oct, p 166

Industry fitness
executives' health: Asia vs US, Jun, p 40
Injuries: see also individual sport, anatomical site
health care in secondary schools, Mar, p 169
larynx, management of, Apr, p 100
in patients in a sports medicine facility, Oct, p 73
and psychological well-being on the US Alpine Ski Team, Oct, p 111
Sorbothane pads for soft-tissue injuries, Jan, p 139
sports, in secondary school boys and girls: a three-year comparison, Mar, p 106
using cold for sports injuries, Jan, p 148
Insurance
liability claims increase in amateur football, Feb, p 161
Inversion
effects on hypertensive subjects, Mar, p 85
oscillating, effects of, Mar, p 93; (letter) Jul, p 15

Knee
braces: prophylactic, rehabilitative, functional (an overview), Sep, p 153
braces for the unstable knee, Feb, p 142; (letter) Jun, p 21
Knee injuries
anterior cruciate ligament, in relay tricycle racing, Jun, p 121
braces, prophylactic, in football, Sep, p 27; p 75
in dancers: arthroscopic assessment and treatment, Nov, p 74
patellalgia, Jul, p 43
pogo stick vs Orthotron in rehabilitation (letter), Jan, p 15
in runners, May, p 127
ski bindings leave knee vulnerable, Dec, p 99
a 12-year study of football injuries at The Pennsylvania State University, Jan, p 102

Larynx
injuries, management of, Apr, p 100
Law and legal medicine
boxing: three bills pending in Congress, Jul, p 33
malpractice and sports medicine, Aug, p 165; p 168
Ligaments
and tendons: electrical stimulation for repair, Aug, p 108
Lipid
blood, profiles in diabetic adolescents after exercise, Dec, p 83

Marathons
atrial fibrillation and flutter in athletes, Mar, p 57
heat stress: diagnosis, treatment vary, Jul, p 134
interest in running fading in Britain, May, p 151
knee disorders in runners, May, p 127
medical complaints in cool weather, Oct,

continued

Capsules
Ointment
IV
Unit Dose
NITRO-BID®
(nitroglycerin)
3/84

vicodin®

hydrocodone bitartrate 5 mg (Warning: May be habit forming) with acetaminophen 500 mg

INDICATIONS AND USAGE: For the relief of moderate to moderately severe pain.
CONTRAINDICATIONS: Hypersensitivity to acetaminophen or hydrocodone.
WARNINGS
Drug Abuse and Dependence: VICODIN is subject to the Federal Controlled Substances Act (Schedule III). Psychic dependence, physical dependence, and tolerance may develop upon repeated administration of narcotics; therefore, VICODIN should be prescribed and administered with the same caution appropriate to the use of other oral-narcotic-containing medications.
Respiratory Depression: At high doses or in sensitive patients, hydrocodone may produce dose-related respiratory depression by acting directly on brain stem respiratory centers. Hydrocodone also affects centers that control respiratory rhythm, and may produce irregular and periodic breathing.
Head Injury and Increased Intracranial Pressure: The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a preexisting increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.
Acute Abdominal Conditions: The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions.
PRECAUTIONS
Special Risk Patients: VICODIN should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture.
Information For Patients: VICODIN, like all narcotics, may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery; patients should be cautioned accordingly.
Cough Reflex: Hydrocodone suppresses the cough reflex; caution should be exercised when VICODIN is used postoperatively and in patients with pulmonary disease.
Drug Interactions: The CNS-depressant effects of VICODIN may be additive with that of other CNS depressants. When combined therapy is contemplated, the dose of one or both agents should be reduced. The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone. The concurrent use of anticholinergics with hydrocodone may produce paralytic ileus.
Usage in Pregnancy: Pregnancy Category C. Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. VICODIN should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Nonteratogenic Effects: Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The intensity of the syndrome does not always correlate with the duration of maternal opioid use or dose.
Labor and Delivery: Administration of VICODIN to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used.
Nursing Mothers: It is not known whether this drug is excreted in human milk; therefore, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
Pediatric Use: Safety and effectiveness in children have not been established.
ADVERSE REACTIONS
Central Nervous System: Sedation, drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, dizziness, psychic dependence, mood changes.
Gastrointestinal System: Nausea and vomiting may occur; they are more frequent in ambulatory than in recumbent patients. Prolonged administration of VICODIN may produce constipation.
Genitourinary System: Ureteral spasm, spasm of vesical sphincters and urinary retention have been reported.
Respiratory Depression: (See WARNINGS.)
DOSAGE AND ADMINISTRATION: Dosage should be adjusted according to the severity of the pain and the response of the patient. However, tolerance to hydrocodone can develop with continued use, and the incidence of untoward effects is dose related.
The usual dose is one tablet every six hours as needed for pain. (If necessary, this dose may be repeated at four-hour intervals.) In cases of more severe pain, two tablets every six hours (up to eight tablets in 24 hours) may be required.
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5688

index continued

p 103
muscle damage in runners (letter), Feb, p 15
overtraining and increased early morning heart rate, Aug, p 77
physiology of marathon running, Jan, p 84; (correction) Mar, p 16
psychological profile of the average female runner, May, p 171
race injuries: runners' perceptions, Nov, p 43
ureteropelvic junction obstruction in long-distance runners, Jul, p 105

Massage
for athletes: therapy, conditioning, techniques, Oct, p 178

Mountain climbing
altitude sickness, Nov, p 36

Muscle
lactic acid and muscle fatigue, Jun, p 193

Muscle injuries
muscle damage in marathon runners (letter), Feb, p 15

National Athletic Trainers Association
public awareness campaign launched, Nov, p 40

National Collegiate Athletic Association
drug testing proposal set for January vote, Dec, p 49
drug testing proposal stalled, Apr, p 26
study: 4% of athletes surveyed used steroids, Aug, p 30

National Football League Players Association
and artificial turf, Sep, p 29

Neck injuries
football, still frequent, Aug, p 29

Novich, Max
boxing vet defends the sport, Apr, p 145

Nutrition
appetite, exercise, and holiday treats, Dec, p 115
bee pollen, Jul, p 159
caffeine and sports performance, May, p 191
calcium and healthy bones, Sep, p 179
dehydration: prevention and treatment, Mar, p 176
eating disorders in young athletes, Nov, p 88
eating nutritiously on the road, Nov, p 133
female runners eat little, Aug, p 30
glucose polymer drinks to be marketed, Sep, p 175
inadequate in adolescent ballerinas, Oct, p 79
status of, in elite ballet dancers, May, p 43

Obesity
iron deficiency, Jan, p 131
nutrient intake in Nordic skiers, Feb, p 78
physical education for obese children, May, p 119
the pregame meal: whatever works, Jan, p 29

Older athletes
Senior Olympic Games (Maryland), Aug, p 159

Olympic Games
blood doping, Mar, p 37
cyclists try caffeine suppositories, Mar, p 38
stiffer penalties for drug abusers, Jul, p 31

Osteoporosis
and calcium, Sep, p 179

Overuse injuries: see also anatomical site, individual sport
in cyclists, prevention of, Oct, p 116
hip, in athletes, Oct, p 131
in young female gymnasts, Dec, p 51

Pelvis
overuse and traumatic injuries in athletes, Oct, p 131

Performance
and psychological well-being on the US Alpine Ski Team, Oct, p 111
and sleep, Nov, p 40

Peripheral vascular disease
popliteal artery occlusion in a wrestler, Aug, p 139

Physical education
and childhood obesity, May, p 119
reemphasis needed, study shows, Jan, p 30

Physicians
primary care (symposium, ACSM annual meeting), Aug, p 145

Physiological studies
marathon running, Jan, p 84; (correction) Mar, p 16
professional baseball players, Jun, p 63
sailors, Olympic-class, Jun, p 152
soccer players, Apr, p 53; (letter) Jul, p 21

Pregnancy
and exercise, Aug, p 145

Psychology
achieving higher performance levels, Feb, p 61
the average female runner: a profile, May, p 171
US Alpine Ski Team: a study, Oct, p 111

Rebound exercise
effects on aerobic capacity and body composition, Nov, p 110
fitness benefits uncertain, Sep, p 141

Rehabilitation
ankle supports evaluated, May, p 59
braces for the unstable knee, Feb, p 142; (letter) Jun, p 21
cardiac, and DRGs, Sep, p 159
clinic provides treatment with health club atmosphere, Sep, p 28
compression for controlling edema, Jun, p 96; (letter) Oct, p 17
fitness facilities as a resource, Oct, p 61
of performing artists at new institute, Sep, p 175
pogo stick vs Orthotron for knee injuries (letter), Jan, p 15
strengthening hip abductors and adductors, Jul, p 161

Running
atrial fibrillation and flutter in athletes, Mar,

continued

p 57
child distance runners, characteristics of, Sep, p 45
female runners eat little, Aug, p 30
interest fading in Britain, May, p 151
medical complaints after cool-weather marathons, Oct, p 103
minutes and miles per week reported in survey, Oct, p 50
muscle damage in marathoners (letter), Feb, p 15
organizing road races for children, Mar, p 126
overtraining and increased early morning heart rate, Aug, p 77
physiology of marathon running, Jan, p 84; (correction) Mar, p 16
psychological profile of the average female runner, May, p 171
the runner's high, Apr, p 166
ureteropelvic junction obstruction in long-distance runners, Jul, p 105

Running injuries
in distance races: runners' perceptions, Nov, p 43
heat stress: diagnosis, treatment vary, Jul, p 134
knee disorders, May, p 127
the side stitch, May, p 187
ureteropelvic junction obstruction, Jul, p 105

Safety
knee braces: required for USFL linemen, Jun, p 37

Sailing
body profile of Olympic-class sailors, Jun, p 152

Senior Olympics
Maryland Senior Olympic Games, Aug, p 159

Shoulder injuries
in canoeists and kayakers: prevention and treatment, Sep, p 120
swimmer's shoulder: influence of flexibility and weight training, Aug, p 92; (correction) Oct, p 23

Ski injuries
and alcohol, May, p 27
bindings leave knee vulnerable, Dec, p 99
in handicapped skiers, Dec, p 93
mirrored sunglasses can cause burn (letter), Mar, p 16

Skiing
cross-country resorts in Montana and Wyoming, Feb, p 173
nutrient intake in Nordic skiers, Feb, p 78
US Alpine Ski Team: a psychological study, Oct, p 111

Skin disease
abrasions treated with medicated ice, Aug, p 155
cancer in female golfers, Aug, p 51
sunburn, Jul, p 81

Sleep
and athletic performance, Nov, p 40

Soccer
demands of the game, physiology of players, Apr, p 53; (letter) Jul, p 21

Spine injuries
football: annual survey, 1977-1983, Mar, p 75

Sports injuries
in patients in a sports medicine facility, Oct, p 73
in secondary school boys and girls: a three-year comparison, Mar, p 106

Sports medicine
ACSM 1985 annual meeting: questions and answers, Aug, p 145
clinic, how to start one, Jun, p 168
epidemiology finds a place on the team, Mar, p 135
and the health care market today, Jan, p 116
health care in secondary schools, Mar, p 169
larynx, management of, Apr, p 100
and malpractice lawsuits, Aug, p 165; p 168
professional organizations listed, Nov, p 143
a team effort, Apr, p 72
at the University of Wisconsin Hospital Sports Medicine and Fitness Center, Jan, p 42; p 51; p 57; p 67

Sprains
ankle, treated with external compression and early mobilization, Jun, p 83
compression for controlling edema, Jun, p 96; (letter) Oct, p 17

Stationary cycling
benefits of, types of cycles, Oct, p 161

Strength
and power, Jul, p 155
strengthening hip abductors and adductors, Jul, p 161

Stress
in the office (letter), Mar, p 16

Sunburn
treatment and prevention, Jul, p 81

Surveys and polls
drugs: attitudes toward abuse and screening in college athletes, Sep, p 93
of fitness in Canadian women, Jan, p 30
football injuries, catastrophic, 1977-1983, Mar, p 75
health-related behavior in 16 states, Oct, p 50

Swimming
effects of reduced training on muscular power, Feb, p 94

Swimming injuries
swimmer's shoulder: influence of flexibility and weight training, Aug, p 92; (correction) Oct, p 23

Tendons
and ligaments: electrical stimulation for repair, Aug, p 108

Testing procedures
assessing body composition, May, p 76
for fitness evaluation in professional baseball players, Jun, p 63
fitness: school children to be tested nationwide, Sep, p 28
fitness testing and conditioning programs for professional hockey players, Nov, p 119
measuring your aerobic fitness, Feb, p 194
predicting your aerobic fitness, Mar, p 183
at the University of Wisconsin Hospital Sports Medicine and Fitness Center, Jan, p 67

Thermography
computer-assisted, for diagnosing stress fractures, Apr, p 114

Tobacco
smokeless, potential health risks of, Oct, p 171

Trainers
NATA launches public awareness campaign, Nov, p 40
at the University of Wisconsin Hospital Sports Medicine and Fitness Center, Jan, p 57

Training
conditioning programs for professional hockey players, Nov, p 119
exercise and beta-blockers, Jul, p 60
rebound exercise: effects on aerobic capacity and body composition, Nov, p 110
reduced: effects on muscular power in swimmers, Feb, p 94

Trampolines
rebound exercise: fitness benefits uncertain, Sep, p 141; Nov, p 110

Travel
cross-country ski resorts in Montana and Wyoming, Feb, p 173
diarrhea, travelers', Nov, p 63
eating nutritiously on the road, Nov, p 133
fishing in the Winnipeg area, May, p 179
Palm Beach and environs, Mar, p 173

Vision
eye care and athletes, Jun, p 132
visual skills often overlooked in sports, Mar, p 37

Water sports
body profile of Olympic-class sailors, Jun, p 152
canoe and kayak injuries: prevention and treatment, Sep, p 120
fitness benefits, Aug, p 180

Weight reduction
physical education for childhood obesity, May, p 119

Weight training
leg strength training equipment compared, Feb, p 49
Nautilus Express Circuit and cardiorespiratory fitness, Apr, p 82
strength vs power, Jul, p 155
strengthening hip abductors and adductors, Jul, p 161
and swimmer's shoulder, Aug, p 92; (correction) Oct, p 23

Wilderness
medicine, Nov, p 36

Wrestling injuries
popliteal artery occlusion, Aug, p 139

Wrist injuries
bracing against hyperextension, Apr, p 163
in canoeists and kayakers: prevention and treatment, Sep, p 120